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NOV 3 0 2005

510(k) SUMMARY

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-9191 Fax
Contact:	Jean Callow
Date Prepared:	May 11, 2005

B. Trade Name: Medcomp Split Cath® II
Common Name: Hemodialysis Catheter, Implanted
Classification: MSD
C.F.R. Section: 876.5540

C. Predicate Device: K020465 Medcomp® Ash Split Cath® II
K884375 Argon Medical Corp. Translumbar Aortography Needle Catheter.

D. Device Description:

The Medcomp Split Cath® II is a polyurethane, double lumen catheter used to remove and return blood through two-segregated lumen passages. Both lumens are "D" shaped, tapered at the distal tip, with three side holes on each tip. The distal venous lumen extends beyond the arterial lumen to reduce recirculation. The fixed polyester cuff allows for tissue ingrowth for long term placement.

The arterial and venous lumens are designed to be split, or peeled apart, prior to insertion to provide two free-floating lumens within the vessel. The side holes are orientated to allow 360-degree arterial uptake and venous return. The lumens are connected to the extensions via a soft pliable hub with suture wing. Red and blue luer connectors and clamps identify the arterial and venous extensions. Priming volume information is printed an identification ring housed within the extension line clamp.

E. Intended Use:

The Medcomp Split Cath® II is indicated for use in attaining long-term vascular access for hemodialysis and apheresis in the adult patient. It may be inserted percutaneously and is primarily placed in the internal jugular vein. Alternate insertion site is the subclavian vein or inferior vena cava as required.

Catheters greater than 40cm are intended for femoral insertion or inferior vena cava insertion. Translumbar insertion via inferior vena cava is indicated only when all other access sites are identified as non-viable.

F. Comparison to Predicate Device:

The technological characteristics of the Split Cath® II are identical to the predicate device in terms of design, design specifications, performance, manufacturing process and method of sterilization.

The difference between the proposed device and the predicate is the inclusion of inferior vena cava as insertion site. Labeling indicating translumbar placement instructions and indicating that translumbar placement of the catheter is a useful and reliable alternative for patients that require long-term hemodialysis but all other access sites are identified as non-viable.

G. Performance Data:

In Vitro performance data for the legally cleared Medcomp Ash Split Cath® II, included tensile strength, joint strength, leakage, recirculation, flow performance, and flexural apply to the Split Cath® II since there are no significant material or design changes. Performance data is submitted for peel testing and force @ break only due to a change in solvent from the predicate device (solvent was cleared under K972207). Chemical testing is submitted for recent ointment testing performed by Medcomp.

Biocompatibility testing on the Ash Split Cath® II demonstrates the lumen materials meet the requirements of ISO 10993 for a permanent contact device. Biocompatibility data on the Split Cath® II was not deemed necessary since substantial equivalence is addressed by way of comparison to a legally marketed device.

Clinical data is based on numerous published clinical papers on the need for and presently used translumbar technique for catheter insertion. Due to criteria stressed in the published clinical papers this technique is for a very small patient population as an absolute last resort when all other traditional access sites have been exhausted. Properly inserted catheters via the translumbar technique do not have a detrimental affect on the clinical outcome as to catheter function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

NOV 3 0 2005

Ms. Jean Callow
Regulatory Specialist
MedComp®
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K051280
Trade/Device Name: MedComp 14F Split Cath II for Translumbar Insertion
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: November 9, 2005
Received: November 28, 2005

Dear Ms. Callow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K051280

Device Name: SPLIT CATH® II CATHETER

Indications for use:

THE MEDCOMP SPLIT CATH® II CATHETER IS INDICATED FOR USE IN ATTAINING LONG TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS IN THE ADULT PATIENT.

IT MAY BE INSERTED PERCUTANEOUSLY AND IS PRIMARILY PLACED IN THE INTERNAL JUGULAR VEIN.

ALTERNATE INSERTION SITES INCLUDE THE SUBCLAVIAN VEIN AND INFERIOR VENA CAVA AS REQUIRED.

CATHETERS GREATER THAN 40CM ARE INTENDED FOR FEMORAL VEIN OR INFERIOR VENA CAVA INSERTION. TRANSLUMBAR INSERTION VIA INFERIOR VENA CAVA IS INDICATED WHEN ALL OTHER ACCESS SITES ARE IDENTIFIED AS NON-VIABLE.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

David A. Lyssy

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051280

(Optional Format 1-2-96)